Complete Summary

GUIDELINE TITLE

Guideline on informed consent.

BIBLIOGRAPHIC SOURCE(S)

American Academy of Pediatric Dentistry (AAPD). Guideline on informed consent. Chicago (IL): American Academy of Pediatric Dentistry (AAPD); 2005. 2 p. [11 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Procedures for which informed consent is necessary

GUIDELINE CATEGORY

Treatment

DISCLAIMER

CLINICAL SPECIALTY

Dentistry Pediatrics

INTENDED USERS

Dentists Physicians

GUIDELINE OBJECTIVE(S)

To provide recommendations for obtaining informed consent from patients receiving oral health care

TARGET POPULATION

Patient or, in the case of a minor or incompetent adult, the custodial parent or legal guardian who is providing informed consent for oral health care

INTERVENTIONS AND PRACTICES CONSIDERED

Informed consent for oral health care procedures

MAJOR OUTCOMES CONSIDERED

Adequate informed consent

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

This guideline was developed through consultation with medical and legal experts and a review of literature, including a MEDLINE search utilizing the terms "informed consent", "pediatric consent", and "consent".

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The oral health policies and clinical guidelines of the American Academy of Pediatric Dentistry (AAPD) are developed under the direction of the Board of Trustees, utilizing the resources and expertise of its membership operating through the Council on Clinical Affairs (CCA).

Proposals to develop or modify policies and guidelines may originate from 4 sources:

- 1. The officers or trustees acting at any meeting of the Board of Trustees
- 2. A council, committee, or task force in its report to the Board of Trustees
- 3. Any member of the AAPD acting through the Reference Committee hearing of the General Assembly at the Annual Session
- 4. Officers, trustees, council and committee chairs, or other participants at the AAPD's Annual Strategic Planning Session

Regardless of the source, proposals are considered carefully, and those deemed sufficiently meritorious by a majority vote of the Board of Trustees are referred to the CCA for development or review/revision.

Once a charge (directive from the Board of Trustees) for development or review/revision of an oral health policy or clinical guideline is sent to the CCA, it is assigned to 1 or more members of the CCA for completion. CCA members are instructed to follow the specified format for a policy or guideline. All oral health policies and clinical guidelines are based on 2 sources of evidence: (1) the scientific literature; and (2) experts in the field. Members may call upon any expert as a consultant to the council to provide expert opinion. The Council on Scientific Affairs provides input as to the scientific validity of a policy or guideline.

The CCA meets on an interim basis (midwinter) to discuss proposed oral health policies and clinical guidelines. Each new or reviewed/revised policy and guideline is reviewed, discussed, and confirmed by the entire council.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Once developed by the Council on Clinical Affairs (CCA), the proposed policy or guideline is submitted for the consideration of the Board of Trustees. While the board may request revision, in which case it is returned to the council for modification, once accepted by majority vote of the board, it is referred for Reference Committee hearing at the upcoming Annual Session. At the Reference Committee hearing, the membership may provide comment or suggestion for alteration of the document before presentation to the General Assembly. The final document then is presented for ratification by a majority vote of the membership present and voting at the General Assembly. If accepted by the General Assembly, either as proposed or as amended by that body, the document then becomes the official American Academy of Pediatric Dentistry (AAPD) oral health policy or clinical guideline for publication in the AAPD's Reference Manual and on the AAPD's Web site.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Informed consent is the process of providing the patient or, in the case of a minor or incompetent adult, the custodial parent or legal guardian with relevant information regarding diagnosis and treatment needs so that an educated decision regarding treatment can be made by the patient or custodial parent or legal guardian. Statutes and case law of individual states govern informed consent. Some states allow oral discussions, which should be documented in the medical record, while others may require written consent. Oral health practitioners should review applicable state laws to determine their level of compliance. Consent forms should be procedure specific, utilize simple terms, and avoid overly broad statements.

When a practitioner utilizes an "informed consent" form, the following should be included:

- 1. Name and date of birth of pediatric patient
- 2. Name and relationship to the pediatric patient/legal basis on which the person is consenting on behalf of the patient
- 3. Description of the procedure in simple terms
- 4. Disclosure of known adverse risk(s) of the proposed treatment specific to that procedure
- 5. Professionally-recognized or evidence-based alternative treatment(s) to recommended therapy and risk(s)
- 6. Place for custodial parent or legal guardian to indicate that all questions have been asked and adequately answered
- 7. Places for signatures of the custodial parent or legal guardian, dentist, and an office staff member as a witness

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated for each recommendation. In general, all oral health policies and clinical guidelines are based on 2 sources of evidence: (1) the scientific literature; and (2) experts in the field.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- The informed consent process allows the patient or the custodial parent or, in the case of minors, legal guardian to participate in and retain autonomy over the health care received.
- Informed consent also may decrease the practitioner's liability from claims associated with miscommunication.

POTENTIAL HARMS

Not stated

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005

GUIDELINE DEVELOPER(S)

American Academy of Pediatric Dentistry - Professional Association

SOURCE(S) OF FUNDING

American Academy of Pediatric Dentistry

GUIDELINE COMMITTEE

Council on Clinical Affairs

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Council members are asked to identify potential conflicts of interest; none was disclosed.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the <u>American Academy of Pediatric Dentistry</u> Web site.

Print copies: Available from the American Academy of Pediatric Dentistry, 211 East Chicago Avenue, Suite 1700, Chicago, Illinois 60611

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

 Overview. American Academy of Pediatric Dentistry 2007-08 definitions, oral health policies, and clinical guidelines. Available in Portable Document Format (PDF) from the American Academy of Pediatric Dentistry Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on August 7, 2007. The information was verified by the guideline developer on August 23, 2007.

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